

WHAT IS CLAIMED IS:

1 1. A computer implemented method for managing a stability study, the
2 method comprising:
3 generating one or more interfaces for the stability study, wherein the one or
4 more interfaces define requirements for the stability study;
5 displaying the one or more interfaces;
6 receiving input information for the one or more interfaces, the received input
7 information for fulfilling the requirements; and
8 validating the received input information against business rules to determine if
9 the input information is acceptable.

1 2. The method of claim 1, further comprising if the input information is
2 acceptable, storing the input information.

1 3. The method of claim 1, further comprising:
2 determining if the requirements for the stability study have been completed;
3 and
4 if the requirements have not been completed, outputting an interface for
5 additional input information for the requirements that have not been completed.

1 4. The method of claim 1, further comprising:
2 determining if approval from a user is needed for the input information.

1 5. The method of claim 4, further comprising:
2 receiving an indication of approval from the user; and
3 storing the indication.

1 6. The method of claim 5, wherein the indication comprises at least one
2 of an electronic signature and captured signature.

1 7. The method of claim 5, further comprising:
2 receiving an indication from the user of disapproval;
3 determining requirements that need to be completed for approval; and
4 outputting an interface needed to complete the determined requirements.

1 8. The method of claim 1, wherein the one or more interfaces include an
2 interface for a stage in a plurality of stages in the stability study.

1 9. The method of claim 8, wherein the plurality of stages comprise at
2 least two of a stability study setup criteria, stability study planning criteria, initial sampling
3 and testing criteria, stability study launch criteria, stability study testing criteria, and stability
4 study evaluation criteria.

1 10. The method of claim 1, further comprising outputting information
2 summarizing the stability study.

1 11. The method of claim 1, further comprising determining a result of the
2 stability study.

1 12. The method of claim 11, wherein the result is inputted by a user.

1 13. A computer implemented method for managing a stability study, the
2 method comprising:

3 (a) determining a criterion in a plurality of criteria needed to complete the
4 stability study;

5 (b) outputting information for one or more requirements for the criterion;

6 (c) receiving information needed to complete the one or more
7 requirements for the criterion based on the information outputted;

8 (d) validating the received information to determine if the one or more
9 requirements are satisfied; and

10 (e) if the one or more requirements have been satisfied, repeating steps
11 (a)-(e) for another criteria in the plurality of criteria until the plurality of criteria have been
12 completed.

1 14. The method of claim 13, wherein the plurality of criteria comprise at
2 least two of a stability study setup criteria, stability study planning criteria, initial sampling
3 and testing criteria, stability study launch criteria, stability study testing criteria, and stability
4 study evaluation criteria.

1 15. The method of claim 13, further comprising storing the received
2 information.

1 16. The method of claim 13, further comprising:
2 determining if the requirements for the criterion have been completed; and
3 if the requirements have not been completed, outputting information needed
4 for the requirements that have not been completed.

1 17. The method of claim 13, further comprising:
2 determining if approval from a user is needed for the criterion.

1 18. The method of claim 17, further comprising:
2 receiving an indication of approval from the user; and
3 storing the indication.

1 19. The method of claim 18, wherein the indication comprises at least one
2 of an electronic signature and captured signature.

1 20. The method of claim 17, further comprising:
2 receiving an indication from the user of disapproval;
3 determining requirements that need to be completed for approval; and
4 outputting an interface needed to complete the determined requirements.

1 21. The method of claim 13, further comprising storing at least a portion of
2 the received information.

1 22. The method of claim 13, further comprising outputting information
2 summarizing the stability study.

1 23. The method of claim 13, further comprising:
2 receiving specifications for establishing the stability study; and
3 generating the plurality of criteria based on the specifications.

1 24. The method of claim 13, wherein validating the received input
2 information comprises validating the received input information against business rules that
3 define whether input information is acceptable.

1 25. The method of claim 13, further comprising determining a result of the
2 stability study.

1 26. The method of claim 25, wherein the result is inputted by a user.